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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,400	12/20/2001	Diana Zanini	VTN-568	3607
27777	7590	02/09/2005	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			CHOI, FRANK I	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 02/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/028,400	Applicant(s) ZANINI ET AL.	
	Examiner Frank I Choi	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-72 is/are pending in the application.
- 4a) Of the above claim(s) 25-72 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☒ Claim(s) 18-24 is/are objected to.
- 8) ☒ Claim(s) 1-72 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claims 18-24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 10-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over by JP 05-269181 or EP 1 050 314, each in view of the acknowledged prior art, Vanderlaan et al. (US Pat. 5,998,498) and Laskey (US Pat. 3,929,741) for the reasons of record in further view of JP 55-38855.

JP 05-3269181 teaches an antimicrobial soft contact lens comprising an antimicrobial substance, such as an acrylacetonate or benzoyl acetate complex of silver, ranging from 0.1 to 20% by weight, polymers of monomers, which include vinyl, allyl group, acrylic groups and/or methacrylic groups, including acryloyloxyethyl phthalic acid, acryloyloxyethyl succinate and methacryloyloxyethyl succinate, phenyl acrylate, phenyl methacrylate, benzy methacrylate and acrylamide (paragraphs 0009-0012, 0024-0026). Specific examples of soft contact lenses are taught containing 69.7 w% 2-hydroxyethyl methacrylate, 24.6 w% methyl methacrylate, 0.4 w% ethylene glycol dimethacrylate and 5w% silver acrylacetonate or 5w% silver benzoyl acetate

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(paragraphs 0052-0055). It is taught that the amount of the antibacterial substance to be added depends on the maintenance of transparency and antimicrobial activity (paragraph 0028).

EP 1 050 314 disclose an antimicrobial contact lens containing silver, in an amount such that preferably no other separate disinfection procedure is necessary, where the polymeric material may comprises polymers which are synthetic, naturally occurring, or combination thereof, including silicone polymers, polyolefins, polyesters, poly urethanes, acrylic, hydrogel-forming polymers, polycarbonates and combinations thereof, including poly-HEMA, polyacrylimide, polydimethyl siloxane, PVP, silicone-acrylate or other hydrophilic contact lens material and the like, provided that the polymer or copolymer should be optically clear and otherwise useful as a contact lens material (Paragraphs 0042-0043, 0048, 0051). It is disclosed that the antimicrobial metal ion is present in a concentration from about 0.01 to 5wt. % of the zeolite which is present in the polymer in a concentration of about 0.01 to 5wt.% (Paragraph 0038).

Applicant acknowledges that soft contact lenses based on hydrogels are widely used because they are more comfortable but that extended use encourages the build of bacteria and other microbes (Pg. 1). It is acknowledged that examples of these soft contact lens, include etafilcon A, balafilcon A, aquafilcon A, lenefilcon, lotrafilcon and silicone hydrogels (Pg. 20, lines 1-8).

Vanderlaan et al. teach that soft contacts can be prepared from silicone hydrogels which combine silicone containing monomers and hydrophilic monomers (See entire reference, especially column 5).

Laskey teaches that hydrophilic monomers of acrylamido sulfonic acid or sulfonate are suitable for soft contact lenses and have greater water retention and because of a greater ability for cross-linking have increased flexibility in the modification of physical properties (Column 1).

JP55-38855 disclose that 2-acryl amide-2-methyl propane sulfonic acid binds with antimicrobial metal, such as silver, which when formulated into films, including porous films, provides a time-releasable antimicrobial material having long-term effectiveness (See entire English translation of JP 55-38855, especially Pgs. 2-6, 9-13 thereof).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose an antimicrobial contact lens comprising silver and a polymer comprising a monomer of formula I. However, the prior art amply suggests the same as antimicrobial soft contact lenses containing silver and monomers falling within the scope of formula I are disclosed by the prior art. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation the soft contact lenses produced would have antimicrobial properties and be time-releasable while having long-term effectiveness and, thus, avoid the problems associated with extended wear.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

Applicant argues that none of the references disclose or suggest that the monomers of Formula I, when polymerized into a contact lens formulation, could reversibly bind silver. However, JP55-38855 discloses that the antimicrobial metal is slowly released over time.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

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Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over by JP 05-269181 or EP 1 050 314, each in view of the acknowledged prior art and Vanderlaan et al. (US Pat. 5,998,498), in further view of Mueller (US Pat. 5,011,275) or Rostoker et al. (US Pat. 4,038,264) for the reasons of record in further view of JP 55-038855.

JP 05-3269181, EP 1 050 314, the acknowledged prior art, Vanderlaan et al. and JP 55-038855 are cited for the same reasons as above and are incorporated herein to avoid repetition.

Mueller discloses a copolymer having high clarity, high hydrophilicity, high oxygen permeability which, in the water swollen state, is soft and flexible, which is suitable for use in soft contact lenses and preferably contains 0.1-10 percent by weight of an ethylenically unsaturated sulfonic acid, such as 2-methacrylamido-2-methyl propane-sulfonic acid (Column 3, Column 4, lines 1-43, Column 12, lines 6-22, Column 6, lines 19-23).

Rostoker et al. disclose that minor amounts of sodium 2-acrylamide-2-methylpropane sulfonic acid, up to 40 percent by weight, to modify the properties of a water-insoluble, hydrophilic polymer which is especially suitable for preparing contact lenses (Column 1, Column 2, lines 1-25, Column 9, Column 10).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose an antimicrobial contact lens comprising silver and a polymer comprising a monomer of formula I. However, the prior art amply suggests the same as antimicrobial soft contact lenses containing silver and monomers falling within the scope of formula I are disclosed by the prior art. As such, it would have been well within the skill of one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation the soft contact lenses produced would have antimicrobial properties and be time-releasable while having

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long-term effectiveness and, thus, avoid the problems associated with extended wear and that minor amounts of 2-acrylamide-2methylpropane sulfonic acid can be used to modify the properties of the polymer as desired with the expectation of arriving at a polymer suitable for use in contact lens.

Examiner has duly considered Applicant's arguments but deems them unpersuasive for the same reasons as above.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Gary Kunz, can be reached at 571-272-0887. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

FIC February 4, 2005



S. MARK CLARDY
PATENT EXAMINER
GROUP 1200

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